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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,623	11/01/2001	Peter J. Oefner	STAN-212	1933

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BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER	
SAKELARIS, SALLY A	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,623	OEFNER ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,32,33 and 50-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29,32,33 and 50-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is written in response to applicant's correspondence submitted 5/21/2004. Claims 28, 33 and 52-55 are amended, claims 1-27 have been canceled, and no claims have been added. Claims 28-29, 32-33, and 50-55 as they relate to the elected Haplotype group II are pending. Applicant should note that claim 28 should be amended to cancel the non-elected subject matter. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 28-29, 32-33, and 50-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 28-29, 32-33, and 50-55 are indefinite over the recitation of "haplotype Group II" and the markers M249, M247, and M150. These claim limitations make the claims unclear because the specification does not define what is specifically encompassed by haplotype Group II's, markers M249, M247, and M150. The issue is that, the ordinary practitioner, when reading this specification to practice the method as claimed, is unable to do so because the disclosure is

unclear, vague and indefinite. What are, in a structural sense, markers M249, M247 and M150? Are these 3 markers defining mutations of haplotype Group II? If so, why are they excluded from Table 2, and furthermore why isn't M60 seen as being exemplary enough to be included with M249, M247, and M150? Furthermore, are these specific markers found consistently in individuals of a specific geographic region? It is not clear what applicant's table 3 is intended to teach. To which haplotype # do each of M249, M247, and M150 correspond and how many people have tested positive for the presence of these markers? Further, what allele is had by each of those people that do carry one of the markers M249(A or G?), M247(T or C?), and M150(C or T?)? There is no fixed definition in the art for what constitutes M249, M247, and M150 or "the plurality of polymorphisms that is representative of allelic forms of at least one haplotype Group II". This last issue is particularly indefinite. If the specification does not identify whether, i.e. M249 in a particular haplotype is an A or a G, it is completely vague and indefinite what has been invented(as well as not described). It is even furthermore vague and indefinite what applicant intends to claim if neither nucleotide given as polymorphic variants are present in their sequence submission of the claimed markers e.g., neither the A or G are present at position 313 of SEQ ID NO: 735(M249)see written description rejection for further explanation. It is therefore unclear, e.g. to what the claim limitations refer. The claims should be amended to clarify to what specific presence/absence of a particular allele that are indicative of the particular ethnic origin of a male.

Response to Arguments:

Applicant's arguments filed 5/21/2004 have been fully considered but they are not persuasive. Haplotypes are known to represent a known relationship between two or more SNPs. Applicant's invention remains unclear because the characteristics and composition of "haplotype

Group II" is not definite. In table 2, "haplotype Group II" is shown to include only M60, while in Table 3, "haplotype Group II" is shown to be represented in populations from Sudan, Ethiopia, and Sardinia without listing any corresponding markers, and even further in Table 4, "haplotype Group II" is shown to be represented by M181, M249, M42, M94, M251, and M299. No where in the specification is applicant's invention of "haplotype Group II" comprised by M249, M247 and M150 disclosed. Regardless of a restriction requirement, applicant should have elected those SNPs that comprise their elected haplotype group, "haplotype Group II". The disclosure is unclear as to what markers comprise "haplotype Group II". The applicant could pick any combination of SNPs, as long as they corresponded to a single haplotype group. The combination they selected, was indefinite in the claims as presently written considering the disclosure is unclear as to which polymorphisms "haplotype Group II" is composed. While applicant's amendments are acknowledged, they are not deemed to make the claims definite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 28-29, 32-33, and 50-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses the markers of SEQ ID NO:735(M249), SEQ ID NO:729(M247), and SEQ ID NO:449(M150) of haplogroup II and the corresponding primer pairs(SEQ ID NOS: 735 and 736, 730 and 731, and 450 and 451 respectively) with which to amplify these markers. Claims 28-29, 32-33, and 50-55 are directed to encompass sequences

that characterize haplotype Group II and the above markers of M249, M247, and M150. A review of the full content of the specification indicates that the detection of the sequences SEQ ID NO:735(M249), SEQ ID NO:729(M247), and SEQ ID NO:449(M150) and each allelic variant, are essential to the operation and function of the claimed invention. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:735(M249) with a G at position 313, SEQ ID NO:729(M247)with a C at position 224, and SEQ ID NO:449(M150)with a T at position 146, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides that are to be detected in haplotype group II of this method as a determinant of a male's ethnic origin, regardless of the complexity or simplicity of the method of isolation. If applicant's invention is the method for determining the ethnic origin of a male by analyzing markers with a specific nucleotide present, none of the nucleotides proposed in the specification to be present are disclosed in the specification as filed as being part of the same haplotype group II. The specification is void of any teaching of these three markers belonging to "haplotype Group II", and any structural explanation as to why the three markers are exemplary for the "haplotype Group II". In table 2, "haplotype Group II" is shown to include only M60, while in Table 3, "haplotype Group II" is shown to be represented in populations from Sudan, Ethiopia, and Sardinia without listing any corresponding markers, and even further in Table 4, "haplotype Group II" is shown to be represented by M181, M249, M42, M94, M251, and M299. Nowhere in the specification is applicant's invention of "haplotype Group II" comprised by M249, M247 and M150 disclosed. Even if arguendo, the disclosure did disclose the nucleotides to be a part of the same haplotype group II, whose detection is considered by applicant to be the invention, the

structure had in common by these markers to cause their placement in the same haplotype group II is not taught by the specification i.e., Adequate written description requires more than a mere statement that the sequence is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

No evidence showing the presence of one or the other nucleotides is present in the claimed haplotype group in the specification. As a result, the specification lacks possession of this haplotype. Therefore, none of the structures encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments:

Applicant's arguments filed 5/21/2004 have been fully considered but they are not persuasive. Applicant's IUB codes are acknowledged, and as such the disclosure of the nucleotides at the polymorphic sites are also acknowledged. However, there is still no recitation in the claims of a sequence that corresponds to any of the markers or their respective SNPs. While Table 1 discloses the markers and their IUB coded SNPs with the SEQ ID NOS: listed that correspond to each marker, such limitations cannot be read into the claims. The disclosure is still lacking written description concerning the "haplotype Group II" distinctions and the lack of a contextual sequence in the claims. As stated above, it is unclear what M249 structure, M247 structure, and M150 structure exists and further why their structures place each of these markers in "haplotype Group II". Furthermore, the specification is void of any teaching of these three markers belonging to "haplotype Group II", and any structural explanation as to why the three markers are exemplary for the "haplotype Group II". In table 2, "haplotype Group II" is shown to include only M60, while in Table 3, "haplotype Group II" is shown to be represented in populations from Sudan, Ethiopia, and Sardinia without listing any corresponding markers, and even further in Table 4, "haplotype Group II" is shown to be represented by M181, M249, M42, M94, M251, and M299. Nowhere in the specification is applicant's invention of "haplotype Group II" comprised by M249, M247 and M150 disclosed. While the amendments to the claims are acknowledged, as stated in the previous office action, the sequence disclosure did not disclose the nucleotides whose detection is considered by applicant to be the invention.

--NEW REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS TO THE CLAIMS--

3. Claims 53 and 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

In the instantly rejected claims, the new limitation of "M150, wherein the nucleotide at position 313 is thymine" in claim 53 and "M150, wherein the nucleotide at position 313 is thymine" in claim 55 appears to represent new matter. Previously the SNP was located at position 146(see specification page 81), not at 313. No specific basis for this limitation was identified in the specification, nor did a review of the specification by the examiner find any basis for the limitation. Since no basis has been identified, the claims are rejected as incorporating new matter.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris

8/2/2004

JEFFREY FREDMAN
PRIMARY EXAMINER
8/3/04